# Evusheld™ Receives Health Canada Approval for Treatment of Covid-19

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*Evusheld is the first long-acting antibody (LAAB) combination to receive Health Canada authorization for both the prevention and treatment of COVID-19*

*Evusheld significantly reduced risk of severe COVID-19 or death in TACKLE Phase III treatment trial*

**MISSISSAUGA, ON, October 18, 2022** – AstraZeneca's *Evusheld*™ (tixagevimab and cilgavimab), a long-acting antibody combination has received a Notice of Compliance from Health Canada for the treatment of mild to moderate COVID-19 in adults and adolescents (≥12 years of age weighing at least 40 kg).[i] This approval follows AstraZeneca's announcement in April that *Evusheld* had been approved as a preventative treatment for COVID-19 and is already available across Canada.

"Certain Canadians continue to be vulnerable to poor outcomes from COVID-19 and having a new treatment option in our arsenal, particularly one that is given as a single dose, is especially welcome news as we move into the winter months when we expect case counts to rise," said Dr. Zain Chagla, Associate Professor, Medicine, Faculty of Health Sciences, McMaster University. "Studies show long-acting antibodies can play an effective role in both treatment and prevention of COVID-19. Evusheld has already made an impact preventing infection in vulnerable populations, such as the immune-compromised, and now has the potential to play an important role in COVID-19 treatment, making sure that high risk patients have even more access to therapeutic options."

The approval by Health Canada was based on results from the TACKLE Phase III treatment trial, which demonstrated reduced risk of severe COVID-19 or death in high-risk patients.[ii]

"Today's approval marks an important step in our ongoing journey to reduce the impact of COVID-19 on the lives of Canadians," said Kiersten Combs, President of AstraZeneca Canada. "*Evusheld* is now the only long-acting antibody combination approved for both prevention and treatment of COVID-19 in Canada, allowing us to help protect even more people who are immune-compromised and remain most vulnerable to this devastating disease."

In TACKLE, one intramuscular (IM) dose of *Evusheld* provided clinically and statistically significant protection against progression to severe COVID-19 or death from any cause compared to placebo. *Evusheld* treatment earlier in the disease course led to more favourable outcomes. TACKLE was conducted in non-hospitalized adults with mild-to-moderate COVID-19 who were symptomatic for seven days or less. 90% of trial participants were at high risk of progression to severe COVID-19 due to co-morbidities or age. *Evusheld* was generally well tolerated in the trial.[ii] The recommended dose of *Evusheld* for treatment in Canada is 300mg of tixagevimab and 300mg of cilgavimab, administered as two separate, sequential IM injections.

*Evusheld* has been shown to retain *in vitro* neutralization activity against the main Omicron variants currently circulating globally, including BA.5.[iii iv]

*Evusheld* is the only long-acting antibody combination with positive Phase III data in the prevention and treatment of COVID-19.[v vi]

**About TACKLE**

TACKLE is a Phase III, randomized, double-blind, placebo-controlled, multi-centre trial assessing the safety and efficacy of a single 600mg IM dose of *Evusheld* (300mg each of cilgavimab and tixagevimab) compared to placebo for the treatment of mild-to-moderate COVID-19. The trial was conducted in 95 sites in the US, Latin America, Europe and Japan. 903 participants were randomized (1:1) to receive either *Evusheld* (n = 452) or saline placebo (n = 451), administered in two separate, sequential IM injections.

Detailed results from TACKLE, published in *The Lancet Respiratory Medicine*, showed *Evusheld* significantly reduced the relative risk of progressing to severe COVID-19 or death (from any cause) by 50% (95% confidence interval [CI] 15, 71; p=0.010) through day 29 compared to placebo in non-hospitalized patients with mild-to-moderate COVID-19 who were symptomatic for seven days or less, the trial's primary endpoint. In pre-specified analyses, the risk reduction was 67% (95% CI 31, 84) compared with placebo when non-hospitalized participants received *Evusheld* within five days of symptom onset.[ii]

**About *Evusheld***

*Evusheld*, formerly known as AZD7442, is a combination of two long-acting antibodies – tixagevimab (AZD8895) and cilgavimab (AZD1061) – derived from B-cells donated by convalescent patients after SARS-CoV-2 infection. Discovered by Vanderbilt University Medical Center and licensed to AstraZeneca in June 2020, the human monoclonal antibodies bind to distinct sites on the SARS-CoV-2 spike protein[vii] and were optimized by AstraZeneca with half-life extension and reduction of Fc effector function and complement C1q binding. The half-life extension more than triples the durability of its action compared to conventional antibodies;[viii ix x] data from the Phase III PROVENT trial show protection lasting at least six months.[i xi] The reduced Fc effector function aims to minimize the risk of antibody-dependent enhancement of disease – a phenomenon in which virus-specific antibodies promote, rather than inhibit, infection and/or disease.[xii]

*Evusheld* is authorized for use for pre-exposure prophylaxis (prevention) of COVID-19 in Canada, the US (emergency use), EU, Japan and many other countries. *Evusheld* is approved for treatment of those with risk factors for severe SARS-CoV-2 infection in the EU and Japan (emergency use).

**About AstraZeneca Canada**

AstraZeneca is a global, innovation-driven biopharmaceutical business with a focus on the discovery, development, and commercialization of medicines that transform lives. Our core scientific focus is in the areas of Cardiovascular, Renal and Metabolic (CVRM) disease; Oncology; Rare Disease; Respiratory & Immunology; and Vaccine & Immune Therapies. AstraZeneca operates in more than 100 countries and its innovative medicines are used by millions of patients worldwide. In Canada, the company employs more than 1,200 people across Canada, including roughly 700 employees at our head office and clinical research hub in Mississauga, Ontario. For more information, please visit the company's website at www.astrazeneca.ca.

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